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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/528,104
Filing Date: September 28, 2005
Appellant(s): HEINZEL ET AL.

Anthony J. Zelano
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/30/08 appealing from the Office action mailed 1/28/08 and the Advisory Action mailed 5/23/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: The rejection of claims 1-4, 6-10, 14, 22, and 28 under 35 U.S.C. 102(b) as being anticipated by MacLeod (WO 00/71703) is currently maintained. However, the rejection of claim 28 under 35 U.S.C. 112, first paragraph, was withdrawn in the Advisory Action of 5/23/08 and should not to be reviewed on appeal.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

"Antisense RNA" (Wikipedia article)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 6-10, 14, 22, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Macleod et al (WO 00/71703 A2; 11/30/00).

Macleod et al teaches the claimed method. Macleod et al teaches a method for the characterization of a HDAC inhibitor or potential HDAC inhibitor (antisense constructs which inhibit the expression of HDAC-2 polypeptide) comprising using an antibody specific for HDAC-2 polypeptide to determine in a sample the amount of HDAC-2 polypeptide, where the sample is derived from cells which have been treated with antisense constructs which inhibit the expression of HDAC-2 polypeptide (Example 3, in particular). Example 3 of Macleod et al illustrates a profile of said antisense constructs based on the ability of antisense constructs to down-regulate the expression of HDAC protein. Macleod et al further teaches a method wherein said sample is derived from a tissue affected by a neoplastic disorder (Example 3 and page 2, in particular). Macleod et al teaches methods involving using any type of neoplastic cell (see lines 28-30 on page 3, in particular). Macleod et al further teaches a method wherein inhibitors are selected by the ability to inhibit the expression of HDAC-2 polypeptide (see Example 3, in particular). Macleod et al further teaches a method comprising the step of determining in a reference sample the amount of HDAC-2 polypeptide wherein the reference sample is derived from cells which have not been

treated with said HDAC-2 inhibitor or potential HDAC-2 inhibitor (see Example 3, in particular). Macleod et al further teaches a method of identifying antisense constructs which decrease expression of HDAC and inhibit proliferation, an activity attributed to HDAC, in neoplastic cells as compared to cells not comprising said antisense constructs (see lines 5-8 on page 28, in particular). Further, decreased HDAC-2 expression due to the antisense constructs of Macleod et al would lead to a decrease in HDAC enzymatic activity because HDAC enzymatic activity could not occur from HDAC that would have been present in the absence of said antisense constructs. Therefore, the antisense constructs of Macleod et al inhibit enzymatic activity of HDAC.

(10) Response to Argument

Appellant argues that Macleod et al fails to teach an HDAC inhibitor. Appellant further argues that Macleod et al fails to teach an HDAC inhibitor or potential HDAC inhibitor which is a molecule that "inhibits the enzymatic activity of said HDAC". Appellant further argues that the antisense method taught by Macleod et al, which results in genetic manipulation of HDAC protein expression, is fundamentally different from Appellant's disclosed technique of modulation of enzyme activity using inhibitors. Appellant further cites a Wikipedia article on "Antisense RNA" (see Exhibit A) and argues that pharmacological differences between antisense technology and methods of modulating enzymatic activity with inhibitors are well-recognized in the art. Appellant further argues that Macleod is silent with respect to profiling HDAC inhibitors or potential HDAC inhibitors based on the ability thereof to down-regulate expression of HDAC protein. With respect to claim 28, Appellant argues that the Office has failed to provide

any evidence supporting an argument that the antisense constructs of MacLeod et al would interfere with the catalytic activity of HDAC. Appellant further states that it is well known in the art that activity and levels of enzymes are two separate aspects of enzyme kinetics and that any contention that high level of proteins is equivalent to high level of enzymatic activity is misplaced. The Examiner respectfully asserts that Appellant's arguments are not persuasive.

In regard to arguments that Macleod et al fails to teach an HDAC inhibitor and that Macleod et al fails to teach an HDAC inhibitor or potential HDAC inhibitor which is a molecule that "inhibits the enzymatic activity of said HDAC", the antisense constructs of Macleod et al are HDAC inhibitors which inhibit HDAC enzymatic activity. Decreased HDAC-2 expression due to the antisense constructs of Macleod et al would lead to a decrease in HDAC enzymatic activity because HDAC enzymatic activity could not occur from HDAC-2 that would have been present in the absence of said antisense constructs. Therefore, the antisense constructs of Macleod et al inhibit enzymatic activity of HDAC. Macleod et al further teaches a method of identifying antisense constructs which decrease expression of HDAC and inhibit proliferation, an activity attributed to HDAC, in neoplastic cells as compared to cells not comprising said antisense constructs (see lines 5-8 on page 28, in particular).

In regard to the arguments that the antisense method taught by Macleod et al is fundamentally different from Appellant's disclosed technique of modulation of enzyme activity using inhibitors and the citation of a Wikipedia article on "Antisense RNA" (see Exhibit A) and argument that pharmacological differences between antisense

technology and methods of modulating enzymatic activity with inhibitors are well-recognized in the art, antisense RNA is one know method of inhibiting proteins and the inhibitors of the instant claims encompass the antisense constructs of Macleod et al for the reasons discussed above. Further, inhibitors of the instant claims are not limited to possible inhibitors disclosed in the specification. Clearly, modulation of enzymatic activity can be performed by methods of inhibiting protein expression as well as methods such as binding an inhibitor to a protein's catalytic region to block said protein's enzymatic activity. However, the instant claims are not drawn to using any particular HDAC inhibitor. Instant claims 1-4, 6-9, and 28 are broadly drawn to using any HDAC inhibitor which inhibits enzymatic activity of HDAC. Instant claims 10, 14, and 22 are broadly drawn to using any HDAC inhibitor or potential HDAC inhibitor. For the reasons discussed above, the antisense constructs of Macleod et al are HDAC inhibitors which inhibit the enzymatic activity of HDAC and are HDAC inhibitors or potential HDAC inhibitors.

In regards to the argument that Macleod is silent with respect to profiling HDAC inhibitors or potential HDAC inhibitors based on the ability thereof to down-regulate expression of HDAC protein, Example 3 of Macleod et al illustrates a profile of antisense constructs based on the ability of antisense constructs to down-regulate the expression of HDAC protein wherein said antisense constructs are HDAC inhibitors or potential HDAC inhibitors.

With respect to claim 28, in regards to the argument that the Office has failed to provide any evidence supporting an argument that the antisense constructs of MacLeod

et al would interfere with the catalytic activity of HDAC, the antisense constructs of Macleod et al are HDAC inhibitors which inhibit HDAC enzymatic activity. Decreased HDAC-2 expression due to the antisense constructs of Macleod et al would lead to a decrease in HDAC catalytic activity because HDAC activity could not occur from HDAC-2 that would have been present in the absence of said antisense constructs. Therefore, the antisense constructs of Macleod et al inhibit enzymatic activity of HDAC. Macleod et al further teaches a method of identifying antisense constructs which decrease expression of HDAC and inhibit proliferation, an activity attributed to HDAC, in neoplastic cells as compared to cells not comprising said antisense constructs (see lines 5-8 on page 28, in particular).

In regards to the statement that it is well known in the art that activity and levels of enzymes are two separate aspects of enzyme kinetics and that any contention that high level of proteins is equivalent to high level of enzymatic activity is misplaced, the Examiner is not arguing that a particular quantitative amount of enzymatic activity can be predicted by particular levels of proteins or that particular levels of proteins give rise to a particular quantitated amount of enzymatic activity. Rather, the Examiner asserts that decreased HDAC-2 expression due to the antisense constructs of Macleod et al would lead to a decrease in HDAC catalytic activity because HDAC activity could not occur from HDAC-2 that would have been present in the absence of said antisense constructs. Therefore, the antisense constructs of Macleod et al, which decrease polypeptide expression of HDAC, inhibit enzymatic activity of HDAC.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Sean E Aeder/

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